



## Cycloplegic Effects of Atropine and Tropicamide in Young Children with Refractive Error: A Quasi-experimental Study

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**Abstract:** *Background:* Cycloplegia is the paralysis of the ciliary muscle of the eye, which causes pupil dilation and accommodation paralysis. This can be accomplished by injecting cycloplegic drugs into the conjunctival sac, such as atropine, cyclopentolate, and tropicamide. The aim of this study was to compare the cycloplegic effects of atropine and tropicamide in young children with refractive error. *Methods:* This quasi-experimental study was conducted at the Department of Pharmacology and Therapeutics in collaboration with the Ophthalmology Department of Rajshahi Medical College Hospital, Rajshahi. This study was conducted over 1 year from July 2021 to June 2022. The study involved 49 young children (98 eyes) with an age range of 2-10 years and refractive error at least in one eye as minimum inclusion criteria. The collected data were analyzed using Statistical Package for Social Sciences (SPSS) software, version-23.0. *Results:* A total of 49 young children (98 eyes) with refractive errors were enrolled in the study. Among 59.2% of the respondents' age was between 6 to 8 years. More than half of the respondents were girls, which was proportionately more than boys. Among the respondents 53% had myopia and the remaining had hypermetropia. Here on hyperopic young children (n=23) mean ( $\pm$ SD) value for cycloplegic refraction of both eyes after using 1% atropine eye drop was + 2.98 ( $\pm$ 1.85) D and +2.79 ( $\pm$ 1.89) D after using 1% tropicamide eye drop. Again, on myopic young children (n=26) mean ( $\pm$ SD) value for cycloplegic refraction of both eyes after using 1% atropine eye drop was -4.88 ( $\pm$ 2.86) D and -5.28 ( $\pm$ 3.37) D after using 1% tropicamide eye drop. None of the drugs caused constipation or any psychological problem. 1% tropicamide eye drop caused eye irritation and redness in 12% of the respondents. Using 1% atropine eye drops 38.8%, 4.1% and 2% of young children suffered from fever, dry mouth, and palpitation respectively. Comparing cycloplegic effect of both eye drops on hyperopic and myopic young children difference was found statistically significant ( $p < 0.05$ ). *Conclusions:* It was found that atropine had significantly ( $P < .05$ ) more cycloplegic effect than tropicamide on both hyperopic and myopic young children but atropine produced more adverse effects.

**Keywords:** Cycloplegia, Atropine, Tropicamide, Refraction, Myopia, Hypermetropia.

### Article at a glance:

**Study Purpose:** Comparing the cycloplegic effects of atropine and tropicamide in young children with refractive error.

**Key findings:** Atropine had more cycloplegic effect than tropicamide on both hyperopic and myopic young children but atropine produced more adverse effects.

**Newer findings:** Tropicamide could be used as a cycloplegic agent for cycloplegic refraction during measurement of refractive error in place of gold standard atropine because of its capability to produce effective cycloplegia and less adverse effects than atropine.

**Abbreviations:** D= Diopter, SD= Standard deviation, Df= Degree of freedom.



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**Peer Review Process:** The Journal "The Journal of Teachers Association" abides by a double-blind peer review process such that the journal does not disclose the identity of the reviewer(s) to the author(s) and does not disclose the identity of the author(s) to the reviewer(s).

### Original Researcher Article

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#### How to cite this article:

Rahman MMU, Ara S, Ali MY, Hoque L,

Hasan KMR, Islam M, Jannat A;

Cycloplegic Effects of Atropine and

Tropicamide in Young Children with

Refractive Error: A Quasi-experimental

Study. Taj 2024;37 (1): 132-139.

#### Article history:

Received: December 27, 2023

Revised: January 14, 2024

Accepted: February 28, 2024

Published: April 21, 2024

## INTRODUCTION

Refractive error is the leading cause of vision impairment and the second leading cause of blindness worldwide.<sup>1</sup> According to the World Health Organization (WHO), approximately 153 million people over the age of five are visually impaired as a result of uncorrected refractive defects.<sup>2</sup> There are approximately 12.8 million visually impaired children between the ages of 5 and 15 years, with a global prevalence of 1% due to untreated or insufficiently corrected refractive defects. Refractive errors are considered preventable conditions that might result in visual impairment in youngsters.<sup>1</sup> Cycloplegic refraction is useful in evaluating patients who have decreased vision or ocular deviation. In children, hypermetropia is a refractive defect that causes reduced eyesight.

Children with this syndrome have reading impairments, learning difficulties, low intellect, and sluggish development of visual perceptual skills. Children require cycloplegic refraction due to their high amplitude of accommodation and inability to provide reliable subjective responses.<sup>3</sup> Cycloplegia reduces accommodative intensity by inhibiting ciliary body activity, allowing the targeted refractive error to be measured. This anticholinergic effect inhibits muscarinic receptors in the iris sphincter, causing mydriasis, and in the ciliary muscle, causing cycloplegia.<sup>4</sup> The evaluation of the cycloplegic effect not only allows refraction mistakes to be rectified; but it also expands the eye pupil during the preparation of eyes for ideal ophthalmoscopy evaluation. Cycloplegic refraction is required for the evaluation of eyes with visual impairment. It also aids in the detection of hypermetropia caused by accommodative esotropia and prevents erroneous results in nearsighted settings.<sup>5</sup> Atropine and tropicamide are the most often used cycloplegic drugs.

They work by competing with the muscarinic mediator "acetylcholine," causing contraction of ciliary body muscles to be inhibited. Several studies have found that various Cycloplegic medications vary in their effectiveness. A few researchers have found a significant and others have found no significant cycloplegic effect for several of these drugs.<sup>6</sup> Most doctors agree that cycloplegia is required while doing refractive

examinations on children. Inadequate cycloplegia can result in imprecise refraction and incorrect demonstration and therapeutic techniques. On the other hand, an overdose of cycloplegics may result in harmful medication effects or a patient's pain.<sup>7</sup> As a long-term action, atropine, the most familiar cycloplegic known for use in children, has its distinct qualities and downsides. Atropine was discovered to be the first strong drug in canceling the accommodative reflex by specialists. Atropine and tropicamide are best used to ensure that no lingering accommodative effect is concealed.

Atropine is the best quality level for completing cycloplegia; nevertheless, it takes at least three hours to acquire maximal effect and should be used for three days to produce the requisite cycloplegia. It takes 1 to 2 weeks for the ciliary bodies and pupils to recover from its effects. Tropicamide, once again, has a faster onset of action and achieves maximum effect within 30-45 minutes; its cycloplegic effect wears off after 6-8 hours and has less unpleasant effects.<sup>8</sup> All visual drugs have negative side effects, which can be classified as systemic or visual. When compared to their widespread use, adverse effects from cycloplegic and mydriatic medications are infrequent.<sup>9</sup> Atropine's poisonous effects can be summarized as "visually impaired like a bat; extremely dry like a bone; insane like a hatter; and red like a beetroot." Atropine can cause severe side effects such as overheating, tachycardia, convulsions, and even death.<sup>10</sup> The aim of this study was to compare the cycloplegic effects of atropine and tropicamide in young children with refractive error.

## METHODS

This quasi-experimental study was conducted at the Department of Pharmacology and Therapeutics in collaboration with the Ophthalmology Department of Rajshahi Medical College Hospital, Rajshahi. This study was conducted over 1 year from July 2021 to June 2022. The study involved 49 young children (98 eyes) with an age range of 2 - 10 years and refractive error at least in one eye as minimum inclusion criteria. Data were registered in this study from children visiting the Ophthalmology department of Rajshahi Medical College and Hospital and private eye chambers of Rajshahi, under the supervision of

ophthalmologists. Approval of the Ethical Review Committee in the Rajshahi Medical College had been taken before the starting of data collection.

Data were collected after taking oral consent from the parents of the participating children. Each child was given two regimens of eye drops, regimen 1 (tropicamide) and then, regimen 2(atropine). One drop of 1% tropicamide ophthalmic drop had given thrice at the interval of 5 min upon testing time; refraction was tested 1 hour after the last dropping by advanced retinoscopy. One drop of Atropine 1% ophthalmic drop was given at home 3 times per day for 3 days before the time of the test. The observed data were collected using a case record form. The collected data were analyzed using Statistical Package for Social Sciences (SPSS) software, version-23.0. Descriptive inferential statistical analysis were performed and the results were presented as mean and percentage. Paired t test was performed to compare the results of the groups, where  $p < 0.05$  considered as the level of significance with 95% CI.

#### Inclusion criteria

- Children below ten years of age (2 to 10 years).
- Both male and female children.
- Children suffering from myopia.
- Children suffering from hypermetropia.

#### Exclusion criteria

- Known case of cardiovascular disorder.
- Children who had ophthalmic ailments other than refractive diseases.
- Those children who were squint.
- Children who were hypersensitive to atropine.
- Children who were hypersensitive to tropicamide.
- Children who were non-compliant with the treatment protocol.

## RESULTS

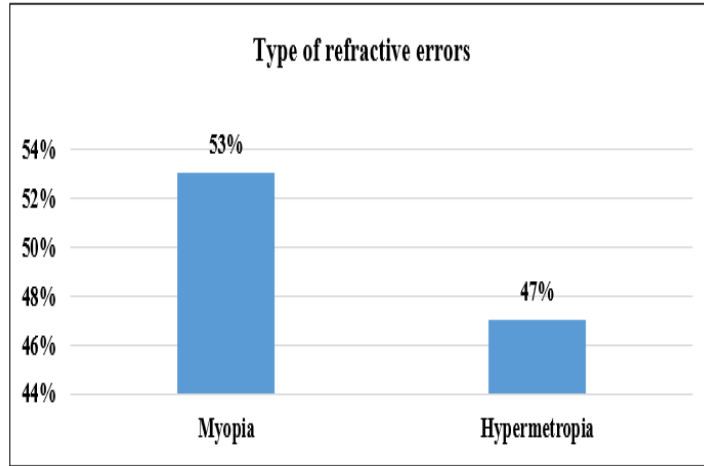
**Table 1: Distribution of respondents according to their age in years (n =49)**

Variable	Frequency	Percent
Age		
3-5 years	17	34.7%
6-8 years	29	59.2%
9-10 years	3	6.1%
Gender		
Boys	23	47%
Girls	26	53%

Mean ( $\pm$ SD) age of the respondents = 5.96 ( $\pm$  1.79) years

Table 1 showed the distribution of the respondents according to their age and gender (n=49). It revealed that 59.2% of the respondents' age was between 6 to 8 years. Only 6.15% of the young children were aged 9 years and above. The mean ( $\pm$ SD) age of the respondents was 5.96 ( $\pm$  1.79)

years. The minimum and maximum ages of the respondents were 3 & 9 years respectively. According to their gender, it revealed that more than half of the respondents were girls (53%), which was proportionately more than boys (47%).



**Figure 1:** Distribution of the respondents according to their refractive errors (n = 49)

Figure 1 showed the distribution of the respondents according to their refractive errors (n = 49). It revealed that more than half (53%) of the

respondents had myopia and the remaining had hypermetropia (47%).

**Table 2: Cycloplegic effect of both eyes drops on both eyes of hyperopic young children (n = 23)**

Different statistical measurements	Cycloplegic refraction on hyperopic young children after using			
	1% atropine eye drop		1% tropicamide eye drop	
	Right eyes (n = 23)	Left eyes (n = 23)	Right eyes (n = 23)	Left eyes (n = 23)
Mean	+2.98 D	+2.98 D	+2.79 D	+2.79 D
Median	+2.50 D	+2.50 D	+2.25 D	+2.25 D
Std. Deviation (±)	1.85 D	1.85 D	1.89 D	1.89 D
Minimum	+0.50D	+0.50D	+0.50D	+0.50D
Maximum	+8.50 D	+8.50 D	+8.50 D	+8.50 D

Table 2 showed the cycloplegic refraction of both eyes of hyperopic young children (n = 23) after using 1% atropine and 1% tropicamide eye drops separately. It revealed that minimum and maximum values of cycloplegic refraction after using 1% atropine drop were +0.50 D and + 8.50 D in

both eyes respectively and its mean (±SD) value was + 2.98 (±1.85) D. Again minimum and maximum values of cycloplegic refraction after using 1% tropicamide eye drop were +0.50 D and + 8.50 D in both eyes respectively and its mean (±SD) value was + 2.79 (±1.89) D.

**Table 3: Cycloplegic effect of both eye drops on both eyes of myopic young children (n = 26)**

Different statistical measurements	Cycloplegic refraction on myopic young children after using			
	1% atropine eye drop		1% tropicamide eye drop	
	Right eyes (n = 26)	Left eyes (n = 26)	Right eyes (n = 26)	Left eyes (n = 26)
Mean	-4.88 D	-4.88 D	-5.28 D	-5.28 D
Median	-4.00 D	-4.00 D	-4.50 D	-4.50 D
Std. Deviation (±)	2.86 D	2.86 D	3.37 D	3.37 D
Minimum	-1.00 D	-1.00 D	-1.00 D	-1.00 D
Maximum	-12.00 D	-12.00 D	-13.00 D	-13.00 D

Table 3 showed the cycloplegic refraction of both eyes of myopic young children (n = 26) after using 1% atropine and 1% tropicamide eye drops separately. It revealed that the mean (±SD)

cycloplegic refraction value after using 1% atropine eye drop was -4.88(±2.86) D on both eyes. Minimum and maximum values of refraction after cycloplegia by 1% atropine drop were -1.0 D and -12.00 D in

both eyes respectively. Mean ( $\pm$ SD) refraction value of myopic young children after cycloplegia by 1% tropicamide eye drop was -5.28 ( $\pm$ 3.37) D on both

eyes. Again, minimum and maximum values of refraction after cycloplegia by 1% tropicamide drop were -1.00 D and -13.00 D in both eyes respectively.

**Table 4: Distribution of adverse effects on myopic and hyperopic young children (n = 49)**

Adverse effects	1 % Atropine eye drop		1% Tropicamide eye drop	
	Yes	No	Yes	No
Eye irritation and redness	0 (0.0%)	49 (100%)	12 (24.5%)	37 (75.5%)
Fever	19 (38.8%)	30 (61.2%)	0 (0.0%)	49 (100%)
Dry mouth	2 (4.1%)	47 (95.9%)	0 (0.0%)	49 (100%)
Constipation	0 (0.0%)	49 (100%)	0 (0.0%)	49 (100%)
Flushing	17 (34.7%)	32 (65.3%)	2 (4.1%)	47 (95.9%)
Palpitation	1 (2%)	48 (98%)	0 (0.0%)	49 (100%)
Psychological problem	0 (0.0%)	49 (100%)	0 (0.0%)	49 (100%)

Table 4 showed the distribution of adverse effects of both eye drops on both myopic and hyperopic young children (n = 49). It revealed that none (0.0%) of the respondents had constipation or any psychological problems after using both eye drops. Fever (38.8%), dry mouth (4.1%), and palpitation (2%) developed among young children

after using 1 % atropine eye drops. Again eye irritation and redness occurred in 12% of the respondents who applied 1 % tropicamide eye drops. Flushing occurred in 34.7% and 4.1% of the respondents after using 1% atropine eye drop and 1 % tropicamide eye drop respectively.

**Table 5: Comparison of the cycloplegic effect of both eye drops on hyperopic young children (n = 23)**

Statistical measurements	Cycloplegic refraction after		t	P
	1% atropine	1% tropicamide		
Mean	+2.98 D	+2.79 D	4.10	<.001
Standard deviation	1.85	1.89		

t = 4.10, df =1, p =0.00

Table 5 showed the comparison of the cycloplegic effect of both eye drops on hyperopic young children (n = 23). A paired samples t-test was used where the mean ( $\pm$  SD) value of

cycloplegic refraction after using 1% atropine +2.98( $\pm$ 1.85) D was more than that of tropicamide +2.79( $\pm$ 1.89) D. The difference was statistically significant (p <.001).

**Table 6: Comparison of cycloplegic effect of both eye drops on myopic young children (n = 26)**

Statistical measurements	Cycloplegic refraction after using		t	P
	1% atropine	1% tropicamide		
Mean	-4.88 D	-5.28 D	2.39	<.05
Standard deviation	2.86	3.37		

t = 2.39, df =1, p =0.025

Table 6 showed the comparison of the cycloplegic effect of both eye drops on myopic young children (n = 26). A paired samples t-test was used where the mean ( $\pm$  SD) value of

cycloplegic refraction after using 1% atropine - 4.88( $\pm$ 2.86) D was more than that of after using 1% tropicamide -5.28( $\pm$ 3.37) D. The difference was statistically significant (p <.001).

## DISCUSSION

In this quasi-experimental study, study population was young children within the age range of 2- 10 years who were suffering from refractive error like hypermetropia or myopia. Here sample size was 49 young children (98 eyes) with refractive error. In this study the age category of the respondent revealed that age of nearly 59.2% of the respondents was between 6- 8 years. A study was conducted among 30 Iraqi children (60 eyes) with hypermetropia whose age range was between 2-9 years, which are almost similar to the present study findings.[4] In this study the distribution of the respondents according to their gender (n=49) revealed that more than half of the young children were girls. In another study boys were more than girls, which was dissimilar to the present study.<sup>11</sup> In this study distribution of the respondents according to their refractive error showed 53% had myopia and the remaining 47% had hypermetropia.

Another study showed prevalence of myopia 59.8% followed by hypermetropia 31.0%. [12] In this study the cycloplegic effect of both eye drops on hyperopic young children (n=23) revealed that the mean ( $\pm$ SD) value of cycloplegic refraction after using 1% atropine eye drop was +2.98 ( $\pm$ 1.85) D on both eyes. The mean refraction ( $\pm$ SD) value of hyperopic young children after cycloplegia by 1% tropicamide was +2.79 ( $\pm$ 1.89) D in both eyes. In another study two drug regimens atropine and tropicamide with cyclopentolate were used for cycloplegia for hyperopic respondents, where the mean ( $\pm$ SD) refraction value was 4.73 ( $\pm$ 2.1) D after using 1% atropine eye drop and 4.54 ( $\pm$ 1.9) D after using 1% tropicamide with cyclopentolate combination eye drop on the right eye. That cycloplegic difference was statistically not significant ( $P > .05$ ). Again, the mean refraction was 4.74 ( $\pm$ 2.0) D after using 1% atropine and 4.54 ( $\pm$ 1.8) D after using 1% tropicamide with cyclopentolate combination on left eye.

That cycloplegic difference was also statistically not significant ( $P > .05$ ).<sup>3</sup> In this study the cycloplegic effect of both eye drops on both eyes of myopic young children (n=26) revealed that the mean ( $\pm$ SD) value of cycloplegic refraction after using 1% atropine eye drop was -4.88 ( $\pm$ 2.86) D on both eyes. The mean ( $\pm$ SD) refraction value of myopic young children after cycloplegia by 1%

tropicamide was -5.28 ( $\pm$ 3.37) D in both eyes. In a study conducted by Manny *et al.*, 2001 showed that only 2 drops of 1% tropicamide was used as a cycloplegic agent for myopic children where mean ( $\pm$ SD) refraction value in the right eye was 0.38 ( $\pm$ 0.41) D, whereas mean ( $\pm$ SD) refraction value in the left eye was 0.30 ( $\pm$ 0.41) D. These findings are not similar to the present study probably due to variation in the age of the respondents between these two studies.<sup>13</sup> In this study, the distribution of adverse effects of both eye drops on both myopic and hyperopic young children (n=49) revealed that none (0.0%) of the respondents had constipation or any psychological problem after using both eye drops. Eye irritation and redness developed in 12% of the respondents who used 1% tropicamide eye drop for their cycloplegia.

Again fever (38.8), dry mouth (4.1%) and palpitation (2%) developed after using 1% atropine eye drop. In a study conducted among 30 Iraqi hyperopic children (60 eyes) who were observed that those who received tropicamide eye drop (regimen 1) didn't show significant side effects compared to that of atropine (regimen 2). There 13.3%, 10%, 16% of children using atropine eye drop suffered from blurred vision, fever, flushing and tachycardia respectively.<sup>4</sup> Here to compare the cycloplegic effects produced by two eye drops applied on hyperopic young children (n=23) a paired sample t- test was done where mean ( $\pm$ SD) value of cycloplegic refraction after using 1% tropicamide on both eyes was 2.79 ( $\pm$ 1.89) D and after using 1% atropine on both eyes was 2.98 ( $\pm$ 1.85) D. On average the cycloplegic effect of 1% atropine on both eyes was 0.19 D more (95% CI) than that of 1% tropicamide eye drop among the hyperopic young children. The difference was statistically significant where  $t(23) = 4.10$ ,  $P < .001$  and two tailed.

In another study two drug regimens (atropine and tropicamide in combination with cyclopentolate) were used for cycloplegia of hyperopic respondents where the mean refraction ( $\pm$ SD) value was 4.73 ( $\pm$ 2.1) D after using 1% atropine and 4.54 ( $\pm$ 1.9) D after using 1% tropicamide in combination with cyclopentolate on right eye. The difference of these cycloplegic effect was statistically not significant ( $p > .05$ ) (Sani *et al.*, 2016). In this study for the comparison of the

cycloplegic effect between two eye drops on myopic young children (n=26) a paired t-test was used where mean ( $\pm$ SD) value of cycloplegic refraction after using 1% tropicamide on both eyes was -5.28 ( $\pm$ 3.37) D and after using 1% atropine eye drop on both eyes was -4.88 ( $\pm$ 2.86) D. On average the cycloplegic effect of 1% atropine eye drop was 0.40 D more, 95% CI than that of 1% tropicamide eye drop among the myopic young children. Another study found that there was no statistically significant difference between the cycloplegic effect of 1% atropine eye drop and 1% tropicamide eye drop.<sup>14</sup>

### LIMITATION OF THE STUDY

The study was conducted in a single center with a small sample size. So, the results may not represent the whole community.

### CONCLUSION

In this study, it was found that atropine had significantly more cycloplegic effect than tropicamide on both hyperopic and myopic young children but atropine produced more adverse effects. Tropicamide might be a suitable alternative in place of atropine to produce effective cycloplegia for refraction in young children with refractive error.

### Recommendations

Short-acting drug tropicamide could be used as a cycloplegic agent for cycloplegic refraction during measurement of refractive error in place of gold standard atropine because of its capability to produce effective cycloplegia and less adverse effects than atropine.

### Acknowledgements

First of all, I would like to thank Almighty Allah for giving me the opportunity, courage and patience to carry out and complete this research work. It is of great pleasure to express my deepest regards and sincere gratitude to my honorable teacher and my research supervisor Prof. Dr. Shahin Ara, Professor and Head, Department of Pharmacology and Therapeutics, Rajshahi Medical College, Rajshahi, whose guidance, constant supervision, valuable suggestions, affectionate advice and whole hearted co-operation made this study success. I am grateful and express thanks to

the member of the Ethical Review Committee for giving kind approval to my research protocol.

I am obliged to Prof. Dr. Nowshad Ali, Principal, Rajshahi Medical College, Rajshahi for his kind permission to conduct this thesis. I pay my humble respect and deep gratitude to all of my respected teachers, Prof. Dr. Shabiha Yasmin Moni, Assistant Professor and Dr. Lotifa Hoque, Department of Pharmacology and Therapeutics, Rajshahi Medical College, Rajshahi for their valuable advice and guidance during my research work. I would like to express my sincere respect and heartfelt gratitude to Prof. Dr. Jawadul Hoque, Vice-Principal, Islami Bank Medical College, Rajshahi from whom I got valuable guidelines to do the research work. I am grateful to my co-guide Associate Professor dr. Md. Yousuf Ali who supported me tremendously and guided me as co-guide for this research work.

I am thankful to my wife Dr. Suraya Parvin, my parents Mosiur Rahman & Mst. Toslima Begum for their support. My special thanks to the lecturers, M.Phil course mates and staff of Department of Pharmacology and Therapeutics, Rajshahi Medical College, Rajshahi for their great support and co-operation. I am also grateful to young children and their parents who helped me by providing necessary data for the research.

### Authors contributions

Professor Dr. Shahin Ara along with Associate Professor Dr. Md. Yousuf Ali and Assistant Professor Dr. Lotifa Hoque helped me (Assistant Professor Dr. Md. Murshid-Ur-Rahman) to select the study topic & formulated the study design of the research work. Associate Professor Dr. Md. Yousuf Ali helped me to fix the method of the study. He also did the retinoscopy examination of the patients. I got help from Assistant Professor Dr. Maryeum Islam during collection of data. Assistant Professor Dr. K. M. Rockybul Hassan & Assistant Professor Dr. Arika Jannat helped me to formulate the table & figures for the data analysis. Along with me *Assistant* Professor Dr. Maryeum Islam analyzed the data. Assistant Prof. Dr. Lotifa Hoque helped me to write the manuscript of the article. Professor Dr. Shahin Ara & Associate Professor Dr. Md. Yousuf Ali supervised & directed

the whole process of the research & manuscript of the article writing.

#### Declarations

**Funding:** 100% Self-funding.

**Conflict of interest:** There is no conflict of interest.

**Ethical approval:** Approval from the ethical committee of the Rajshahi Medical College had been taken before the starting of data collection.

**Consent for publication:** Given to Taj: Journal of Teachers Association by all the authors of this article.

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